

APPLICATION NO.

10/712,799

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KENYON & KENYON LLP

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NEW YORK, NY 10004

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PAPER NUMBER

FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO.

Ilan Kor 1662/53605 7835

EXAMINER

ANDERSON, REBECCA L

ART UNIT

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) |
|---|----------------------------|-----------------------------|
| Office Action Summary | 10/712,799 | KOR ET AL. |
| | Examiner | Art Unit |
| | Rebecca L. Anderson | 1626 |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | |
| Status | | |
| 1) Responsive to communication(s) filed on | | |
| , , | -· action is non-final. | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | |
| Disposition of Claims | | |
| 4)⊠ Claim(s) <u>1-27</u> is/are pending in the application. | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | |
| 5) Claim(s) is/are allowed. | | |
| 6) Claim(s) is/are allowed. | | |
| · · · · · · · · · · · · · · · · · · · | | |
| 7) Claim(s) is/are objected to. | | |
| 8)⊠ Claim(s) <u>1-27</u> are subject to restriction and/or election requirement. | | |
| Application Papers | | |
| 9)☐ The specification is objected to by the Examiner. | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | |
| Priority under 35 U.S.C. § 119 | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | |
| 1. Certified copies of the priority documents have been received. | | |
| 2. Certified copies of the priority documents have been received in Application No | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | |
| | | |
| Attachment(s) | | |
| 1) Notice of References Cited (PTO-892) | 4) Interview Summary (| PTO-413) |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Da | te |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | 5) Notice of Informal Pa | stent Application (PTO-152) |

DETAILED ACTION

Claims 1-27 are currently pending in the instant application and are subject to the following restriction requirement.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-10 and 17-21 drawn to Form VI of Carvedilol, classified in class
 548.
- II. Claims 11-16 drawn to processes for the preparation of Form VI of Carvedilol, classified in class 548.
- III. Claims 22 and 23 drawn to methods of treatment with Form VI of Carvedilol, classified in 514.
- IV. Claims 24-27 drawn to a process of preparing Form II of Carvedilol, classified in 548.

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed, Carvedilol, can be made by another and materially different process as can be seen by page 2 of applicants' specification, which discloses other methods of preparation of crystalline Carvedilol.

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Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product, such as for the treatment of hypertension or the treatment of congestive heart failure.

Inventions I, II and III are independent and distinct from IV as IV is a process for the preparation of the Form II and Inventions I, II and III are related to form VI.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of

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record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rebecca Anderson

Patent Examiner

Art Unit 1626, Group 1620 Technology Center 1600 March 15, 2006